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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,006	08/18/2008	Angela Bardotti	PAT051667-US-PCT	6482

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NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY- X100B
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,006	BARDOTTI ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-34* is/are pending in the application.

4a) Of the above claim(s) *16, 17, 19-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response of 9/26/2010 is acknowledged.

Status of the Claims

2. Claims 1-17 and 19-34 are pending in this application.

Priority

3. Acknowledgment is made of applicants' claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed.

Drawings

4. The drawings submitted 9/15/2006 have accepted by the examiner.

Information Disclosure Statement

5. The information disclosure statement filed 8/18/2008 has been considered. An initialed copy is enclosed. However, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Election/Restrictions

6. Applicants' election with traverse of 9/26/2010 is acknowledged. Applicants elected invention I (claims 1-15 and 32-34). Applicants have not elected species in response to election of species.The examiner withdraws election of species. The traversal is on the ground(s) that "Applicants request that Groups I and II be recombined as both groups share a common special technical feature and relate to a single general inventive concept. In particular, the Group I and Group II claims both require the step of passing the sample through a solid phase extraction device to obtain a specimen comprising separated unconjugated saccharide, i.e., solid phase extraction is used to separate the conjugated saccharide component in the sample from the unconjugated saccharide component (page 2, lines 18-20). Neither Bardotti *et al.* (*Vaccine* 18:1982-1993 (2000)) or EP 0462794) discloses a method having this step, and EP 0462794

does not relate to analysis of a sample's unconjugated saccharide content. Thus Groups I and II share a common technical special technical feature that makes a contribution over the art, and therefore are linked as to form a single general inventive concept. Accordingly, reconsideration of the requirement for restriction between Groups I and II is respectfully requested."

This is not found persuasive because both the first and the second claimed methods do not define a technical feature over the art as evidenced by Bardotti *et al. (Vaccine* 18: 1982-1993, 3 April 2000) whom teach a method of analyzing samples containing unconjugated saccharide content (see abstract). Because the first appearing technical feature does not define a contribution over the art, it is not considered "special" within the meaning of PCT Rule 13.2 and as such the groups lack unity of invention. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the first invention is drawn to a method of analyzing and the second invention is drawn to a method of separating.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-15 and 32-34 are under consideration. Claims 16-17 and 19-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected as being in improper Jepson form. See MPEP § 1.75 (e).

Claims 32-34 are also rejected as being depended from improper claim 3.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Packer et al. (Glycoconjugate Journal vol. 15, pp.737-747, 1998).

The claims are drawn to a method of analyzing a sample's unconjugated saccharide content, comprising the steps of (i) passing the sample through a solid phase extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the specimen's saccharide content to give the unconjugated saccharide content of the sample.

Packer et al. teach a method of analyzing a sample's unconjugated saccharide content, comprising the steps of (i) passing the sample through a solid phase extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the specimen's saccharide content to give the unconjugated saccharide content of the sample (see abstract , Introduction and material and methods). The prior art teach the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-9 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardotti et al. (Vaccine 18: 1982-1993, 3 April 2000) in view of Hennion, MC. (Journal of Chromatography A, vol.856, pp. 3-54 September 24, 1999). Prior art of record.

The claims are drawn to a method of analyzing a sample's unconjugated saccharide content, comprising the steps of (i) passing the sample through a solid phase extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the specimen's saccharide content to give the unconjugated saccharide content of the sample.

Bardotti et al. teach a method of analyzing a sample's unconjugated saccharide content, comprising the steps of(i) passing the sample through an extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the specimen's saccharide content to give the unconjugated saccharide content of the sample (see abstract, material, methods and table 1). Bardotti et al. teach a glycoconjugate vaccine (see page 1983) single and combined vaccine (see table 1) measuring total sacchride content (see tables 1 and 2). Bardotti et al. teach quantitative conjugate analysis techniques, such as high performance anion exchange

chromatography with pulsed amperometric detection (HPAEC-PAD) see abstract. Bardotti et al. do not teach a solid phase extraction device. However, these devices are well known in the art for example Hennion, MC. (Journal of Chromatography A, vol.856, pp. 3-54, September 24, 1999) teach solid phase extraction, its method development and sorbents (see abstract).

It would have been prima facie obvious to one of ordinary skilled in the art at the time of invention to use a solid phase extraction device in the method of Bardotti et al. to obtain the instant invention. One of ordinary skilled in the art would have been motivated by the teachings of Hennion to use a solid phase extraction device (SPE) because of its popularity in sample preparation method and reduction in usage of organic solvents in the laboratories which has encouraged the requirement for solvent free procedures and growth of SPE (see Hennion pages 4-5).

As to limitations of claims 32-34 such as releasing vaccine for use, packaging and adjusting pH. These are considered optimization of experimental parameters. However, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

13. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lei et al. (Dev. Biol (Basel) vol. 103, pp. 259-264, 2000) in view of Hennion, MC. (Journal of Chromatography A, vol.856, pp. 3-54, September 24, 1999). Prior art of record.

The claims are drawn to a method of analyzing a sample's unconjugated saccharide content, comprising the steps of (i) passing the sample through a solid phase extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the specimen's saccharide content to give the unconjugated saccharide content of the sample.

Lei et al. teach a method of analyzing a sample's unconjugated saccharide content, comprising the steps of(i) passing the sample through an extraction device to obtain a specimen comprising separated unconjugated saccharide and (ii) analyzing the

specimen's saccharide content to give the unconjugated saccharide content of the sample (see abstract). Lei et al. teach a glycoconjugate vaccine (see abstract) single and combined vaccine, measuring total sacchride content (see abstract). Lei et al. teach limitations of claims 10-15 meningococcal vaccines prepared from *Neisseria meningitis* serogroups A, C, W 135 and Y (see abstract). Lei et al. teach quantitative conjugate analysis techniques, such as high performance anion exchange chromatography with pulsed amperometric detection (HPAEC-PAD) see abstract. Lei et al. do not teach a solid phase extraction device. However, these devices are well known in the art for example Hennion, MC. (Journal of Chromatography A, vol.856, pp. 3-54 September 24, 1999) teach solid phase extraction, its method development and sorbents (see abstract).

It would have been prima facie obvious to one of ordinary skilled in the art at the time of invention to use a solid phase extraction device in the method of Lei et al. to obtain the instant invention. One of ordinary skilled in the art would have been motivated by the teachings of Hennion to use a solid phase extraction device (SPE) because of its popularity in sample preparation method and reduction in usage of organic solvents in the laboratories which has encouraged the requirement for solvent free procedures and growth of SPE (see Hennion pages 4-5).

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thurs-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571)-272 0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/
Examiner, Art Unit 1645
November 22, 2010

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646